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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,668	08/27/2001	Jens Petersen	60117.000005	2506

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EXAMINER

AZPURU, CARLOS A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 09/938,668	Applicant(s) PETERSEN, JENS	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- Th **MAILING DATE** of this communication app ars on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 17-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 27-35 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-26 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>04112002&1</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the preliminary amendment filed 11/26/2001. Information disclosure statements were filed on 04/11/2002, and 10/31/2003. A response to the restriction requirement was filed on 10/31/2003.

Election/Restrictions

Applicant's election with traverse of Group II in Paper No. 10312003 is acknowledged. The traversal is on the ground(s) that the search of all the groups would not entail an undue burden on this office. This is not found persuasive because In addition to the main classes and subclasses listed for each group, additional search areas would be indicated. For example, in addition to the search of class 528, the hydrogel would need to be cross searched in both class 424 and 514. Group II would necessitate a search of the surgical areas for prostheses. Because of the additional search of these classes and subclasses entailed by Groups I and III, this would indeed entail an undue burden on this office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8, 27-35, and 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10/31/2003.

Claim Rejections - 35 USC § 112

Claims 27-35 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Although applicant sets out the load bearing and chemical characteristics of the polyacrylamide endoprosthesis, there is nothing in the specification would lead the ordinary practitioner to understand how the polyacrylamide hydrogel prevents the disease process known as arthritis. There is no showing of decreased/increased cartilage before and after application, no disclosure showing the difference in inflammation, pain discomfort, or any other diagnostic symptom associated with arthritis. As such, the specification is not enabling for the preventing arthritis.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) The nature of the invention: The invention sets out the use of a polyacrylamide hydrogel as an intraarticular endoprosthesis.

2) The state of the prior art: Common therapy includes the use of anti-inflammatory drugs such as Vioxx or Celebrex. To date, nothing has been found to completely prevent the onset of arthritis.

3)The relative skill of those in the art: These include biomedical researchers and physicians, so the relative skill of those in the art is high.

4) The predictability or unpredictability of the art: Since no long term study has been done on the polyacrylamide prophylactic treatment of joints, there is no way to predict whether arthritis will develop or not. No clinical data provided which would support the "prevention" or even treatment of the disease process. Such a study would necessitate not only reporting of physical diagnostic symptoms such as pain or stiffness, but also measurements of the inflammation within the joints studied over an extended period of time. Without any of these, it is impossible to predict whether arthritis will or will not develop.

5)The breath of the claims: The claim of preventing arthritis is extremely broad in that no parameters are given as to the what would constitute a preventative measure. Does this include inflammation , pain, the number of inflammatory cells?

6) The amount of direction or guidance presented: The specification provides no guidance as to how arthritis is prevented. The disclosure is enabling for an intrarticular endoprosthesis, however, no guidance is given as to the prevention of arthritis symptomology.

7) The presence or absence of working examples: The working examples are all directed towards the method of making the polyacrylamide gel. There are no working examples as to how applicant shows the prevention of arthritis.

8) The quantity of experimentation necessary: As stated above, claim language directed towards the prevention of arthritis would entail exhaustive experimentation and analysis of years of clinical and experimental data. Aside from tracking those with the endoprosthesis, the group would need to be divided into control and experimental groups. Those with family history of arthritis would be of particular concern. Physical diagnosis, cellular and enzymatic analysis of the joints would need to be taken over long periods of time. No experimentation has been made to the level that would guide the ordinary practitioner in showing the prevention of arthritis.

EPO 742022A1 is cited for its disclosure of a polyacrylamide hydrogel endoprosthesis. No disclosure is made as to the prevention of arthritis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca

**CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500**

A handwritten signature in cursive script, appearing to read 'Carlos Azpuru', written in black ink.